

REMARKS

Claims 1-6 and 8-23 are presently pending in the captioned application. The amendments are presented in the expectation that the amendments will place this application in condition for allowance. The amendments do not introduce new matter within the meaning of 35 U.S.C. § 132. Accordingly, entry of the amendments is respectfully requested.

1. Claim for Foreign Priority

The Examiner has objected to the claim for foreign priority for the following reasons:

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Singapore on February 24, 2001. It is noted, however, that applicant has not filed a certified copy of the 200100727-7 application as required by 35 U.S.C. 119(b).

Applicants thank the Examiner for his suggestions regarding the claim for foreign priority. Accordingly, applicants submit herewith a certified copy of the foreign application, SG 200100727-7, to which the present application claims priority. Accordingly, applicants respectfully request the Examiner to remove the outstanding objection and affirm the claim for foreign priority.

2. Information Disclosure Statement

The Examiner has objected to the following informality:

The disclosure does not contain references listed on a proper information disclosure statement. Therefore, unless the references have been cited by the examiner on form PCT-892, applicant should not assume references have been considered.

Applicants thank the Examiner for his suggestions. Applicants note in this regard that an Information Disclosure Statement with an attached PTO-Form 1449 was filed on September 16, 2003 bringing several references to the attention of the Examiner. Accordingly, applicants request an indication from the Examiner that the Examiner has considered these references properly cited in an Information Disclosure Statement.

3. Objection to the Specification

The Examiner has objected to the present specification for the following reasons:

Applicant's attention is directed to page 7 of the specification. The description of Figures 1 and 2 are not properly identified. Appropriate correction is required.

Applicants thank the Examiner for his suggestions regarding the specification. Accordingly, applicants have amended the specification to replace the "Detailed Description of the Present Invention" identifier immediately preceding the description of the two Figures with the proper "Brief Description of the Drawings" identifier. Additionally, following the description of the two Figures, applicants have inserted the proper identifier "Detailed Description of the Invention". Accordingly, applicants respectfully assert that these amendments overcome the Examiner's objection to the specification.

4. Objections to Claims 9-12, 14-19, and 21-23

The Examiner has objected to the claims for the following reasons:

Claims 9-12, 14-19, and 21-23 are objected to because of the following informalities: the abbreviation "HLB" should refer readers to the terms from which said abbreviation arises. Appropriate correction is required. Claim 17 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Applicants thank the Examiner for his suggestions regarding the claims. Accordingly, applicants have amended claims 9-11 and 14 to insert the phrase "Hydrophile-Lipophile-Balance" to identify the meaning for the abbreviation "HLB", as the Examiner requested. Additionally, applicants have amended claim 17 to remove the dependency to the other multiple dependent claim, claim 16.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the objections to claims 9-12, 14-19, and 21-23.

5. Rejection of Claims 1-6, 9-16, and 18-23 under 35 U.S.C. § 112, 2d paragraph

The Official Action states that claims 1-6, 9-16, and 18-23 are rejected under 35 U.S.C. § 112, second paragraph for the following reasons:

Claims 1-6 and 9-16, 18-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "reduced pressure" in claims 1 and 14 is a relative term which renders the claim indefinite. The term "reduced pressure" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant has failed to provide a starting or reference pressure from which a "reduced pressure" is derived. If it is applicant's intention to claim a process in which the pressure is less than atmospheric pressure, the claims should be amended to more precisely reflect applicant's intentions. Claim 19 recites the limitation "workup solvents" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Applicants respectfully traverse this rejection. Regarding the §112, second paragraph rejection, caselaw has defined two requirements under the statute: (1) whether the applicant has stated the invention as something elsewhere in the application which would not fall under the scope of the claims; and (2) whether the claims would be communicated with a reasonable degree of particularity and distinctness to a person skilled in the art in light of the content of the disclosure and the teachings of the prior art. MPEP §2171, §2173, and §2173.02.

Applicants thank the Examiner for his suggestions regarding the claims. Accordingly, applicants have amended claim 1 to insert the limitation of claim 7 specifying that the reduced pressure ranges from 4 to 20 Torr, as suggested by the Examiner. Additionally, applicants have amended claim 19 to correct the insufficient antecedent basis noted by the Examiner.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claims 1-6, 9-16, and 18-23.

6. Rejection of Claim 15 under 35 U.S.C. § 102(b)

The Official Action states that claim 15 is rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,440,027 to Hasenhuettl.

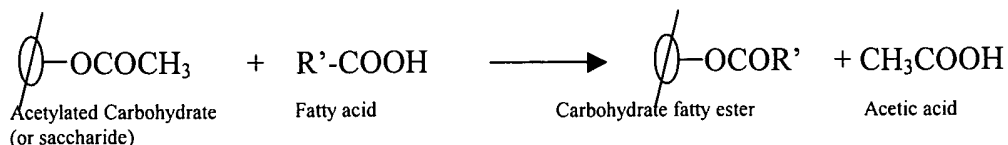
As the basis of this rejection, the Official Action states:

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Hasenhuettl U.S. Patent 5,440,027 (Hasenhuettl).

Hasenhuettl discloses a carbohydrate fatty acid produced via a solvent-free transesterification of acylated carbohydrates under reduced pressure, 1-500 mm Hg, at a temperature of 95-200° C in the presence of an acid catalysts (column 5, lines 56-68; column 3, lines 34-68; column 4, lines 1-2; column 9, lines 56-68; column 11, lines 2-21).

Applicants respectfully traverse this rejection. The test for anticipation is whether each and every element as set forth is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131. The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP §2131. The elements must also be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

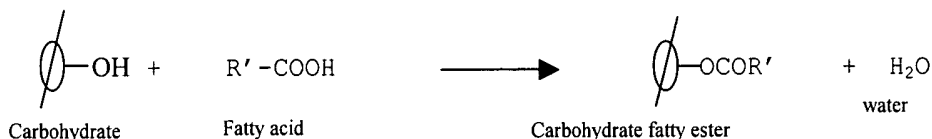
The presently claimed invention relates to carbohydrate fatty acid esters produced according to a solvent-free trans-acidolysis reaction. These carbohydrate fatty acid esters are produced by reacting an acylated carbohydrate, or saccharide, with a free acid, according to the following process:



According to this process, a free acid group is replaced with another free acid, i.e. free acid goes in, free acid comes out. Accordingly, this reaction results in an acetic acid by-product. Further, this process is carried out at temperatures between 60 and 95°C. Accordingly, this process results in the production of surface-active carbohydrate esters of broad range HLB (hydrophile-lipophile-balance) values.

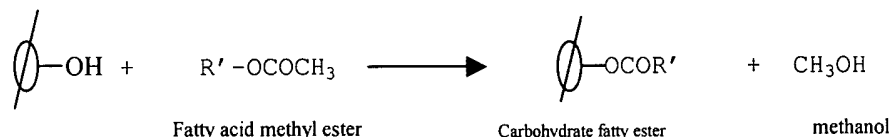
In contrast, Hasenhuettl discloses methods for preparing saccharide fatty acid polyesters by first conducting an esterification, then conducting trans-alcoholysis or trans-esterification.

In particular, the initial esterification reaction is conducted to obtain a partially esterified saccharide which is then subject to trans-alcoholysis and/or trans-esterification. The esterification process is as follows:



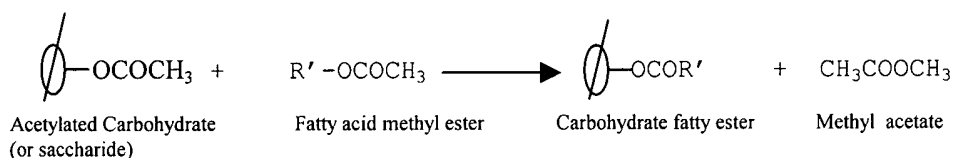
According to this process, a hydrogen atom is replaced with an acid (acyl) group, i.e. free acid goes in, water comes out. The partially esterified saccharide produced according to this process is then subject to a trans-alcoholysis or trans-esterification process.

The trans-alcoholysis reaction requires reacting an alcohol-containing carbohydrate with a fatty acid methyl ester to obtain a carbohydrate fatty ester, as shown by the following process:



According to this process, the initial carbohydrate free alcohol is replaced with another free alcohol, i.e. free alcohol goes in, free alcohol comes out. See col. 4, lines 12-56 of Hasenhuettl, describing R''OH (methanol) as a byproduct of the reaction.

Similarly, the disclosed trans-esterification reaction requires reacting an acetylated carbohydrate, or saccharide, with a fatty acid methyl ester to obtain a carbohydrate fatty ester, as shown by the following process:



According to this process, an acid ester group is replaced with another acid ester, i.e. acid ester goes in, acid ester comes out. Accordingly, this reaction results in a methyl acetate acid by-product. These two reactions disclosed by Hasenhuettl, then, result in different end-products than the reaction taught by the presently claimed invention.

Further, these processes disclosed by Hasenhuettl are carried out at temperatures between 95°C and 200°C. See col. 4, lines 1-2. This temperature is considered too high for many saccharides,

limiting the types of saccharides that can be produced according to the process. Accordingly, the processes of Haenhuettl are only suitable for producing "fat-substitutes or low-calorie fats". See col. 11, lines 28-30. In contrast, the presently claimed carbohydrate fatty acid esters are produced at a lower temperature, i.e. 60-95°C. Accordingly, the claimed carbohydrate fatty acid esters are surface-active carbohydrate esters of broad range HLB (hydrophile-lipophile-balance) values, entirely different compounds than those produced according to the process of Hasenhuettl. Hasenhuettl, then, does not anticipate the presently claimed carbohydrate fatty acid esters.

Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of pending claim 15.

7. Rejection of claims 1-10, 13, 16, and 18-21 under
35 U.S.C. § 103(a)

The Office Action states that claims 1-10, 13, 16, and 18-21 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,440,027 to Hasenhuettl in combination with D'Amato (U.S. Patent No. 3,054,789), Silver et al. (U.S. Patent No. 5,596,085), Matsumoto et al. (U.S. Patent No. 5,008,387), and Heesen et al. (U.S. Patent No. 3,951,945).

As the basis of this rejection, the Official Action states:

Claims 1-10, 13, 16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hasenhuettl U.S. Patent 5,440,027 (Hasenhuettl) in combination with D-Amato U.S. Patent 3,054,789 (D'Amato), Silver et al. U.S.

Patent 5,596,085 (Silver), Matsumoto et al. U.S. Patent 5,008,387 (Matsumoto), and Heesen et al. U.S. Patent 3,951,945 (Heesen).

Claim 1 is drawn to a process for preparing carbohydrate fatty-acid esters comprising: a) reacting acylated carbohydrate with free fatty acid in the presence of an acid catalysts under reduced pressure; b) decolorizing and separating out the unreacted fatty acid from the reaction mixture or step a); c) precipitating out the unreacted acylated carbohydrate from the reaction mixture obtained from step b); and d) recovering carbohydrate fatty ester from the reaction mixture obtained from step c). Claims 2-10, 13, 16, and 18-21 depend from claim 1. Claim 2 is drawn to a process wherein no solvent is added in step a). Claims 3 and 4 limit the manner in which the unreacted fatty acid is removed in step b). Claim 5 limits the temperature range for precipitating the unreacted acylated carbohydrate in step c). Claim 6 is drawn to a process wherein the unreacted fatty acid and acylated carbohydrate is recycled. Claims 7-8 limit the pressure range wherein step a) is carried out. Claims 9-10 are drawn to HLB properties of the products produced. Claim 13 limits the temperature range in which step a) is performed. Claim 16 limits the carbohydrates employed in the process. Claim 18 limits the acid catalyst employed. Claims 19-20 limit the workup solvents. Claim 21 limits the free fatty acids employed.

Hasenhuettl teaches the solvent-free transesterification of acylated carbohydrates under reduced pressure, 1-500 mm Hg, at a temperature of 95-200°C in the presence of an acid catalysts, which meets the sulfuric acid of claim 18 (column 5, lines 56-68; column 3, lines 34-68; column 4, lines 1-2; column 9, lines 56-68; column 11, lines 2-21). Saccharides disclosed as starting materials include glucose, sucrose, and raffinose along with other monosaccharides, disaccharides, and higher polysaccharides (column 7, lines 6-20). Suitable free fatty acids used in the process include butyric, lauric, palmitic, stearic, and oleic acids (column 8, lines 65-68; column 9, lines 1-18). Hasenhuettl further teaches that conventional purification techniques may be employed such as neutralization, dissolution into an organic solvent such as hexane, and decolorization with activated charcoal or hydrogen peroxide.

Hasenhuettl exemplifies purification of the products by distillation and filtration but lacks the recitation of separating the unreacted fatty acid and precipitating the unreacted acylated carbohydrate. Hasenhuettl teaches the

use of partially acylated carbohydrates; however, Silver employs an identical process using partially or fully acylated carbohydrates (sucrose octaacetate) (columns 5-10).

D'Amato teaches a process preparing pure sucrose fatty esters. D'Amato teaches that after removal of the catalyst and neutralization, the resulting mixture is continuously extracted with an organic solvent capable of dissolving the unreacted fatty acid lower alkyl ester or glyceride and the free fatty acid present in the medium, and in which the fatty acid sucrose ester is insoluble, and having a favorable partition coefficient (column 1, lines 61-72; column 2, lines 1-3).

Heesen teaches a method for purifying fatty acid esters of saccharides. Heesen teaches that non-esterified fatty acid can be removed by reaction with a bivalent cation with formation of insoluble calcium fatty acids salts and subsequent filtration, by treatment with ion exchange resins, by fractionated crystallization or a similar treatment, by (molecular) distillation (column 4, lines 15-21).

Matsumoto teaches a process for purifying sucrose fatty acid esters. Masumoto teaches that the removal of the unreacted sucrose from the reaction mixture containing sucrose fatty acid ester has been generally conducted by utilizing the property that sucrose is slightly soluble in common organic solvents, namely by adding a solvent to the reaction mixture to precipitate the unreacted sucrose and removing the precipitate (column 1, lines 39-45).

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare carbohydrate fatty-acid esters by a process comprising: a) reacting acylated carbohydrate with free fatty acid in the presence of an acid catalysts under reduced pressure; b) decolorizing and separating out the unreacted fatty acid from the reaction mixture or step a); c) precipitating out the unreacted acylated carbohydrate from the reaction mixture obtained from step b); and d) recovering carbohydrate fatty ester from the reaction mixture obtained from step c) as Hasenhuettl teaches the transesterification reaction and the product is purified using conventional means. The instantly claimed purification techniques are seen to be well within the purview of one of ordinary skill in the art at the time of the invention. The purification steps of the instantly claimed process are based on the solubility properties of the resultant reaction mixture. The use of solubility properties for purifying carbohydrate fatty

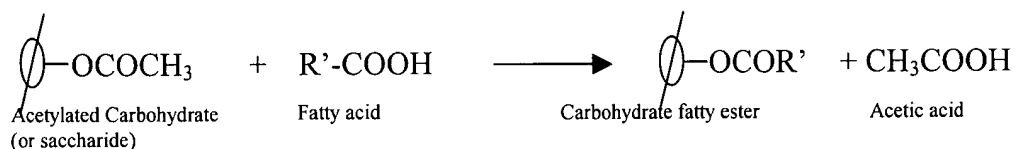
acid esters is well known in the art. The choice of the appropriate solvents, pH, temperatures, and concentrations are seen to be well within the purview of the skilled artisan. The skilled artisan would readily recognize that the precipitation of a given compound is generally enhanced by lowering the temperature of the solution in which it is contained. The specific condition manipulated in order to affect the solubility of a given compound is seen to be a choice of experimental design. It would also have been obvious to one of ordinary skill in the art to recycle the unreacted components of the reaction mixture as it is well established that batch and continuous processes are not patentably distinct. The recitation of HLB values of the product produced is not seen to add any patentable weight to the instantly claimed process as all of the process steps for preparing the carbohydrate fatty acid esters are taught in the art. Where the steps of a process are the same as the prior art, and the only difference is in the recital of the product produced, the process is unpatentable over the prior art.

Applicants respectfully traverse this rejection because all three prongs for a *prima facie* case of obviousness have not been established for each of the rejections. Specifically, all the claim limitations are not present in the cited references and one of ordinary skill in the art would have no motivation to modify the cited references into the present invention.

To establish a *prima facie* case of obviousness, the Examiner must establish: (1) that some suggestion or motivation to modify the references exists; (2) a reasonable expectation of success; and (3) that the prior art references teach or suggest all the claim limitations. In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); Amgen, Inc. v. Chugai Pharm. Co., 18 USPQ2d 1016, 1023 (Fed. Cir. 1991); In re Wilson, 165 USPQ 494, 496 (C.C.P.A. 1970).

A *prima facie* case of obviousness must also include a showing of the reasons why it would be obvious to modify the references to produce the present invention. See Ex parte Clapp, 277 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). The Examiner bears the initial burden to provide some convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings. Id. at 974.

The presently claimed invention relates to a process for preparing carbohydrate fatty acid esters according to a solvent-free trans-acidolysis reaction. This process involves the reaction of an acylated carbohydrate, or saccharide, with a free fatty acid, according to the following process:



According to this process, a free acid group is replaced with another free acid, i.e. free acid goes in, free acid comes out. Accordingly, this reaction results in an acetic acid by-product. Further, this process is carried out at temperatures between 60 and 95°C. Accordingly, this process results in the production of surface-active carbohydrate esters of broad range HLB (hydrophile-lipophile-balance) values.

In contrast, both Hasenhuettl and Silver et al. disclose methods for preparing saccharide fatty acid polyesters by first conducting an esterification, then conducting trans-alcoholysis or

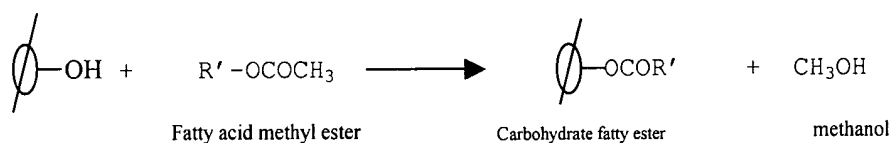
trans-esterification.

In particular, the initial esterification reaction of Hasenhuettl is conducted to obtain a partially esterified saccharide which is then subject to trans-alcoholysis and/or trans-esterification. The esterification process is as follows:



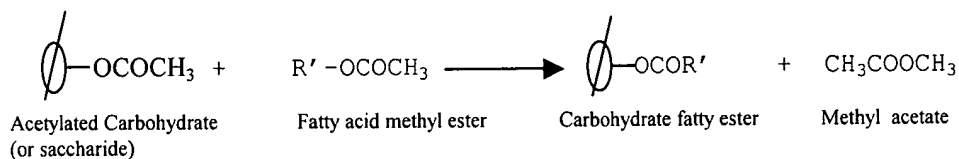
According to this process, a hydrogen atom is replaced with an acid (acyl) group, i.e. free acid goes in, water comes out. The partially esterified saccharide produced according to this process is then subject to a trans-alcoholysis or trans-esterification process.

The trans-alcoholysis reaction of Hasenhuettl and Silver et al. requires reacting an alcohol-containing carbohydrate with a fatty acid methyl ester to obtain a carbohydrate fatty ester, as shown by the following process:



According to this process, the initial carbohydrate free alcohol replaces methanol, another alcohol in fatty acid methyl ester, i.e. free alcohol goes in, free alcohol comes out. See col. 4, lines 12-56 of Hasenhuettl, describing R''OH (methanol) as a byproduct of the reaction.

Similarly, the trans-esterification reaction of Hasenhuettl and Silver et al. requires reacting an acetylated carbohydrate, or saccharide, with a fatty acid methyl ester to obtain a carbohydrate fatty ester, as shown by the following process:



According to this process, an acid ester group is replaced with another acid ester, i.e. acid ester goes in, acid ester comes out. Accordingly, this reaction results in a methyl acetate acid by-product.

Neither Hasenhuettl nor Silver et al. disclose the presently claimed trans-acidolysis reaction. In particular, Hasenhuettl and Silver et al. disclose three different reactions as shown above: esterification, trans-alcoholysis, and trans-esterification.

The esterification process of Hasenhuettl is used to acetylate a simple saccharide to obtain an acetylated saccharide as an end product. In contrast, the presently claimed processes require an acylated carbohydrate as a starting reactant to obtain an end-product carbohydrate fatty acid ester. Accordingly, since the end product of the disclosed esterification process is a starting reactant of the presently claimed trans-acidolysis process, the esterification process of Hasenhuettl clearly does not render the presently claimed process obvious.

Further, the trans-alcoholysis and trans-esterification

processes of Hasenhuettl and Silver et al. both use a fatty acid methyl ester as an initial reactant. Since no organic acid by-products result from these disclosed reactions, it is clear that the fatty-acid containing reagents used to obtain the polyesters are fatty acid methyl esters, resulting in methanol or methyl acetate by-products. See Hasenhuettl, col. 3, lines 12-24; col. 4, lines 44-56; col. 6, lines 3-10; col. 10, lines 43-68; col. 12, lines 24-26; and Silver et al., col. 4, lines 4-28 and 43-53; col. 9, lines 24-32; col. 10, lines 7-9. In contrast, the presently claimed trans-acidolysis process uses a free fatty acid as an initial reactant. This free fatty acid results in an acetic acid, rather than a methanol or methyl acetate, by-product. Accordingly, the presently claimed trans-acidolysis process is clearly neither taught nor described by the Hasenhuettl and Silver et al. references.

None of Matsumoto et al., Heesen et al., and D'Amato et al. references remedy these deficiencies. As the Examiner has admitted on the record, each of these secondary references relate to processes for purifying, not producing, sucrose fatty acid esters. As a result, none of these references are capable of expressly or inherently disclosing in any way a trans-acidolysis process, such as the presently claimed process. Accordingly, since none of the references cited by the Examiner in any way relate to the presently claimed trans-acidolysis process, each and every limitation of the presently claimed invention is not taught by the cited references,

as required by *In re Wilson*. Accordingly, the presently claimed processes are unobvious over the references cited by the Examiner, taken alone or in combination.

Further, the use of the present inventive trans-acidolysis process conveys significant, unexpected advantages over the transesterification processes disclosed by Hasenhuettl and Silver et al. In particular, the degree of esterification of the partially esterified saccharide is crucial to the success of the previous transesterification step, i.e. the degree of esterification must be kept to between 2 and 3 lower acyl ester groups. See Hasenhuettl col. 6, lines 45-61 and Silver et al. col. 5, line 48 to col. 6, line 2. In contrast, there is no such limitation according to the presently claimed trans-acidolysis process.

Similarly, reducing saccharides must first be converted to non-reducing saccharides (i.e. to form glycoside) prior to initial esterification according to the Hasenhuettl process. See Hasenhuettl col. 7, lines 53-59. In contrast, the presently claimed process is a trans-acidolysis process on a saccharide and accordingly has no limitations on reducing saccharides.

These unexpected advantages of the presently claimed process further helps support applicants assertion that the present process is unobvious over the disclosure of the Hasenhuettl and Silver et al. references.

Accordingly, applicants respectfully submit that the presently claimed invention is unobvious over Hasenhuettl in view of Silver

et al., Matsumoto et al., Heesen et al., and D'Amato et al. and respectfully request the Examiner to reconsider and withdraw the rejection of presently pending claims 1-6, 8-10, 13, 16, and 18-21.

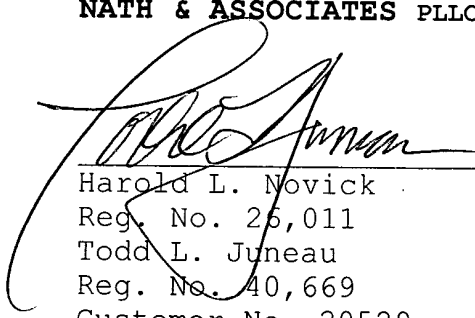
CONCLUSION

In light of the foregoing, applicants submit that the application is now in condition for allowance. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of all pending claims 1-6 and 8-23 and allow these claims. Favorable action with an early allowance of the claims is earnestly solicited.

Respectfully submitted,

NATH & ASSOCIATES PLLC

21 Oct., 2003
NATH & ASSOCIATES PLLC
1030 15th Street, N.W.
6th Floor
Washington, D.C. 20005
Tel: (202) 775-8383
Fax: (202) 775-8396
HLN:JBG:\roa.82306.doc


Harold L. Novick
Reg. No. 26,011
Todd L. Juneau
Reg. No. 40,669
Customer No. 20529